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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,572	10/11/2005	Gerhard Hoefle	930008-2197	5809

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EXAMINER	
ANGELL, JON E	
ART UNIT	PAPER NUMBER
1635	
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12/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,572	HOEFLE ET AL.	
	Examiner	Art Unit	
	J. E. Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *2-6,8 and 10-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 10/2/2008.

Claims 1-34 are currently pending in the application and are addressed herein.

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1, 7, 9) in the reply filed on 10/2/08 is acknowledged. The traversal is on the ground(s) that claim 1 relates to a ssDNA molecule having a sequence according to Figure 1 or a ssDNA molecule 90% identical to that ssDNA molecule and that the size of the sequence must be 90% of the length of Figure 1. Applicants assert that claim 1 does not encompass the 10mers taught by the cited art. This is not found persuasive because claim 1, part (i) is drawn to "an ssDNA molecule having a sequence according to Figure 1"; part (ii) is drawn to, "an ssDNA molecule which is 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, or 100% homologous to an ssDNA molecule according to (i) in respect of its number of nucleotides or its nucleotide sequence but which differs by at least one nucleotide from the ssDNA molecule according to (i) in respect of its number of nucleotides and/or its nucleotide sequence"; and part (iii) specifically recites, "an ssDNA molecule having a sequence which is complimentary to the sequence of an ssDNA molecule according to (i) or (ii)." It is noted that "an ssDNA molecule having a sequence according to Figure 1" encompasses any ssDNA that has ANY sequence of nucleotides present in Figure 1, regardless of the size of the ssDNA. In other words, part (i) does not require that the ssDNA be the same length as the sequence of Figure 1. Furthermore, part (ii) explicitly encompasses any ssDNA molecule that is 90% or more homologous to an ssDNA molecule of (i) in respect of its nucleotide sequence.

Thus, (ii) clearly indicates that the ssDNA can be 90% or more homologous in its sequence to Figure 1. A 10mer oligonucleotide that exactly matches 10 consecutive nucleotides of Figure 1 would be 100% homologous to an ssDNA having a sequence according to Figure 1. Additionally, a sequence which is complementary to an ssDNA of (i) or (ii) would also encompass 10mer oligodeoxynucleotides which are fully complementary to any 10 consecutive nucleotides of (i) or (ii). Thus, claim 1 does not exclude 10mer oligodeoxynucleotide sequences. As such, Applicants agreements are not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 2-6, 8, 10-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/2/2008.

3. Claims 1, 7 and 9 are examined herein.

Information Disclosure Statement

4. The information disclosure statement (IDS) filed 3/4/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Specifically, the IDS cites a non-patent publication by SASSE, however a copy of the cited non-patent publication has not been submitted/received.

Applicants are required to submit a legible copy of the non-patent publication in order to have the publication considered.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication 2001/0053519 (FODOR et al.).

7. As indicated above, claim 1, part (i), is drawn to "an ssDNA molecule having a sequence according to Figure 1"; part (ii) is drawn to, "an ssDNA molecule which is 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, or 100% homologous to an ssDNA molecule according to (i) in respect of its number of nucleotides or its nucleotide sequence but which differs by at least one nucleotide from the ssDNA molecule according to (i) in respect of its number of nucleotides and/or its nucleotide sequence"; and part (iii) specifically recites, "an ssDNA molecule having a sequence which is complimentary to the sequence of an ssDNA molecule according to (i) or (ii)." It is noted that "an ssDNA molecule having a sequence according to Figure 1" encompasses any ssDNA that has ANY sequence of nucleotides present in Figure 1, regardless of the size of the ssDNA. In other words, part (i) does not require that the ssDNA be the same length as the sequence of Figure 1. Furthermore, part (ii) explicitly encompasses any ssDNA molecule that is 90% or more homologous to an ssDNA molecule of (i) in respect of its nucleotide sequence.

FODOR et al. teaches an array comprising all possible 10mers (see Example 2begining on page 12). Therefore, FODOR et al. anticipate claim 1.

8. Claims 1, 7, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,672,500 (LITWACK et al.).

As indicated above, claim 1, part (i), is drawn to "an ssDNA molecule having a sequence according to Figure 1"; part (ii) is drawn to, "an ssDNA molecule which is 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, or 100% homologous to an ssDNA molecule according to (i) in respect of its number of nucleotides or its nucleotide sequence but which differs by at least one nucleotide from the ssDNA molecule according to (i) in respect of its number of nucleotides and/or its nucleotide sequence". It is noted that "an ssDNA molecule having a sequence according to Figure 1" encompasses any ssDNA that has ANY sequence of nucleotides present in Figure 1, regardless of the size of the ssDNA. In other words, part (i) does not require that the ssDNA be the same length as the sequence of Figure 1. Furthermore, part (ii) explicitly encompasses any ssDNA molecule that is 90% or more homologous to an ssDNA molecule of (i) in respect of its nucleotide sequence. Furthermore, claim 7 is drawn to variants or mutants which result from substitution, deletion, or insertion of nucleotides... of an ssDNA according to claim 1, those variants and mutants encoding enzyme variants or enzyme mutants for the production of secondary substance(s) having properties characteristic of tubulysins. It is noted that the second paragraph of the specification reads:

> Tubulysins have a cytostatic or antimitotic action on fungi, human tumours or cancer cell lines and other animal cell cultures (cf. Table). Within the cells, they result in rapid degradation of the microtubule structure. The actin skeleton is preserved. Under the influence of tubulysins, adherently growing L929 mouse cells increase in volume without

> dividing and develop large cell nuclei, **which then break up in an apoptotic process**. (Emphasis added).

Therefore, the specification defines that a characteristic of tubulysins is activation of apoptosis. Therefore, claim 7 encompasses any variant/mutant sequence of claim 1 wherein the variant/mutant sequence encodes an enzyme that is involved in producing a secondary substance that has properties characteristic of tubulysins, which includes activation of apoptosis. Claim 9 encompasses a vector having a DNA molecule according to claim 1.

LITWACK et al. teach an enzyme designated "Mch2" which is described as an enzyme which possess protease activity and can cleave poly(ADP-ribose) (PARP) suggesting that it is involved in PARP cleavage observed during cellular apoptosis. LITWACK et al. characterize Mch2 as a "Ced-3/ICE-like protease and a candidate mediator of apoptosis in mammalian cells." (See column 3, lines 1-10). Furthermore, LITWACK et al. teach the polypeptide sequence of Mch2 (see column 3, lines 35-45) as well a nucleic acid sequence that encodes Mch2 and a recombinant expression vector which comprises a nucleic acid sequence which encodes Mch2 (e.g., see claims 1-16, etc.). Therefore, LITWACK et al. anticipated the instant claims.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 9 recites the broad recitation "A vector", and the claim also recites "especially an expression vector" which is the narrower statement of the range/limitation.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner, Art Unit 1635